



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,011	09/05/2003	Ann M. Maloney	10/041-2-C2	1738

28510 7590 08/01/2005

MICHAEL P. MORRIS  
BOEHRINGER INGELHEIM CORPORATION  
900 RIDGEBURY ROAD  
P O BOX 368  
RIDGEFIELD, CT 06877-0368

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
----------	--------------

1618

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/657,011

**Applicant(s)**

MALONEY, ANN M.

**Examiner**

Blessing M. Fubara

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration and response to the final rejection filed 07/05/05. Claims 50-54 are pending.

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action has been considered and the finality of that action is withdrawn because claim 53 was not addressed in the last office action.

#### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClelland et al. (US 5,350,584) in view of Chow et al. (US 4,859,461) and further in view of Bodmeier et al. ("Effect of ion exchange resins on the drug release from matrix tablets," in European Journal of Pharmaceutics and Biopharmaceutics, 46, (1998), pp 321-327; provided by applicants).

McClelland discloses a formulation that contains a copolymer of acrylic acid and divinylbenzene (AMBERLITE-IRP 64) or styrene-divinylbenzene (AMBERLITE-IRP 69) and oxycodone or hydrocodone as examples of the drugs (column 2, line 62 to column 3 line 2; column 5, lines 13 and 14). The formulation of McClelland further contains excipient selected from polyvinylpyrrolidone, methylcellulose and polyethylene glycol (column 5, lines 45-48). McClelland discloses polyvinylpyrrolidone or methylcellulose as the excipient instead of hydroxypropylmethyl cellulose or hydroxypropyl cellulose or hydroxyethyl cellulose.

Art Unit: 1618

Chow discloses a composition that comprises AMBERLITE-70 and pharmaceutically active basic drugs selected from dextromethorphan, codeine, hydrocodone, morphine and propranolol and an impregnating agent selected from hydroxypropylmethyl cellulose, hydroxypropyl cellulose, sorbitol, hydroxypropyl sorbitol, and polyvinylpyrrolidone for a prolonged continuous release of the active drugs. Chow further discloses that the hydroxyl alkyl celluloses are present in amounts ranging from about 3% to about 20% and that the polyvinylpyrrolidone are present in amounts ranging from 7% to 20%. See column 1, lines 36-58 and column 2, lines 12-63. The particle size of the resin is from about 25  $\mu\text{m}$  to about 1,000  $\mu\text{m}$  (column 2, lines 53-57).

Chow is relied upon for disclosing a combination of hydrocodone and hydroxypropylmethylcellulose or polyvinylpyrrolidone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the oxycodone composition of McClelland and use hydroxypropylmethylcellulose as the carrier. Bodmeier discloses that incorporation of ion exchange resin into hydroxypropylmethylcellulose modifies the release of drugs; and amount and particle size of the resin particles of the carrier influences drug release. Therefore, one having ordinary skill in the art would have been motivated to use the hydroxypropylmethylcellulose and particles having the appropriate size to modify the drug release.

4. Claims 50 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClelland et al. (US 5,350,584) in view of Chow et al. (US 4,859,461) and further in view of applicants admitted prior art.

Art Unit: 1618

McClelland and Chow are discussed above. The combined reference of McClelland and Chow does not include phenolic amine resin. Examples of phenolic amine resins are AMBERLITE IRP-58 (applicants' specification at paragraph [0027] of the published application # 20040062812). Applicants are aware that IRP-58 and IRP-69 are equivalent and as a teaching reference IRP-69 and IRP-70 are equivalent (Eichman, US 5,980,882, column 6, lines 45-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare oxycodone-containing formulation and to substitute IRP-70 or IRP-69 with IRP-58 with the expectation of producing analgesic formulation.

Observation:

In claim 50, line 8, after "or," oxycodone is spelled "oxycodine" and correction is requested.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

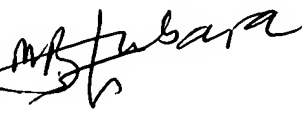
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name and title.